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12/29/94

To: Commissioner of Patents and Trademarks
Washington, D.C. 20231

Re: Response to Examiner's Action mailed 09/12/94
Serial Number : 08/031,562 180 Examiner: Julie Krsek-Staples,Ph.D.
Supervisory Patent Examiner: Christine M. Nucker Group 180

Date of Response

The above Response was made by the Applicant, dated 12/9/94 and sent by *"Express Mail Next Day Service"* on December 11, 1994 (Enclosed: 1. Post Office Receipt #GB976454655; 2. a copy of the Response sent).

Request for 30 Day Extension of Time to Respond

Applicant has been informed by the Examiner that the Response arrived a day later than promised by the Post Office and that a request for a 30-day extension of time to respond should be sent by the Applicant accompanied by a fee of $55. This request is herewith made and a cheque for $55 enclosed.

Additional Information To Be Added to the Response

The Applicant believes that a recent Editorial in the leading scientific journal *Nature* (Vol 372, December 8, 1994, page 485), which has just come to the Applicant's attention, is relevant to the Examiner's Action and to the above Response, and the Applicant requests that the information in this Editorial which is relevant to the above Response be added to the Response and made a part of the record.

The *Nature* Editorial discusses several aspects of the breadth of patent coverage with special reference to vaccines. An example is given of a patent which covers the identification of " an antigenically effective epitope serving as the basis for a reliable blood test" .

Then in discussing the question of whether the knowledge that epitope which serves as the basis for a reliable blood-test makes it obvious that a vaccine could be made from that epitope, the Editorial states:

> **"But an epitope proved effective in a blood-test does not, on that evidence alone, make a vaccine."**

This is precisely the argument made by the Applicant with reference to the Recognins both in the patent application and in the Response.

And the Examiner's two references, Stevenson and Bystryn (see references in Examiner's Action and in Applicant's Response) both agree that requirements other than just the identification of an epitope (antigen), are required to make a vaccine. There is thus unanimity among those of ordinary skill in the art, as well as in one of the most authoritative scientific sources, *Nature*, regarding the criteria for determining and defining a vaccine, and these all agree with the Applicant's criteria.

In the case of the Recognins, the evidence that malignin had proved effective in a blood-test did not, on that evidence alone, make a vaccine. It was not obvious that malignin would make a vaccine; there are many tumor markers which are not and cannot be vaccines. Without discovery of additional properties in areas such as those referred to in the Examiner's references, malignin does not make a vaccine. The other requirements, in the case of the Recognins were the discoveries described in the present application that anti-malignin anitbody is:

1) a highly potent cytotoxic antibody which interacts with an antigen (malignin) in "immune effector mechanisms" (a requirement of Bystryn, Cancer and Metastasis Reviews9:81-91,1990, page 83), in this case the selective destruction of cancer cells; and

2) anti-malignin is a cytotoxic antibody which increases in concentration with age, as the risk of cancer increases.

Therefore the Applicant respectfully suggests that Claims 1 and 2 are now in condition to be allowed.

Respectfully submitted,

Samuel Bogoch.

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